510K SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 17 2007

This summary of 510k safety and effectiveness information is being submitted in accordance with 21CFR part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

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Date of Preparation:
12/5/07

2. Proprietary Name:
ITALITE tm Models: 500-3.1
550-3.1
600-3.1
650-3.1
450-2.0
400-2.0

Common /Usual Name:
Arthroscope

Classification Name: 21 CFR888.1100 Arthroscopes

Classification Number: 90HRX

3. Substantially Equivalent Devices

JG Medical Products LLC believes that the ITALITE tm light wand Models 500-3.1; 550-3.1; 600-3.1; 650-3.1; 450-2.0; 400-2.0 is substantially equivalent to the following cleared devices:

Trade or Proprietary Name	Manufacturer	510(k) Number
Medscope 4mm Arthroscope	Medscope Corp.	k894303
ASAP Arthroscope	ASAP Endoscopic Products	k031972

All of the above predicate Arthroscopes have two fiber optic channels, one for viewing and one for illuminating the subject field. The ITALITE tm light wand models above are made of similar materials, fibers, and epoxies.to the predicate devices above. In fact the ITALITE tm light wand uses exactly the same materials and construction methods as the Medscope 4mm Arthroscope k894303, However the ITALITE tm light wand Models have only an illumination channel and are not used for viewing. Illumination is perpendicular to the shaft.
Substantial equivalence is claimed for the indications for use for this application.

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4. DEVICE DESCRIPTION

The ITALITE tm models of Light Wands range in size as follows:

MODEL	LENGTH	DIAMETER
650-3.1	650 mm	3.1 mm
600-3.1	600 mm	3.1 mm
550-3.1	550 mm	3.1 mm
500-3.1	500 mm	3.1 mm
450-2.0	450 mm	2.0 mm
400-2.0	400 mm	2.0 mm

The ITALITE tm series of Light Wands are semi rigid type devices which are intended for illumination during joint examinations, biopsies, in minimally invasive procedures of the knee, shoulder, temporal mandibular joint, ankle, and elbow.

The device consists of a thin walled stainless steel tube (either 3.1 mm or 2.0 mm) varying in length from 400 to 650 mm depending on the model number as above. 50 micron glass fibers fill the inner diameter of the tube. At the proximal end the fibers are sealed with epoxy and polished. They are terminated in a light pipe connector compatible with off the shelf light sources such as those manufactured by ACMI, Wolff, Stortz, and Olympus. A stainless steel knob at the proximal end facilitates the direction and placement of the Light Wand.

The distal end of the Light Wand has a window perpendicular to the shaft where the fibers terminate. They are epoxied and polished to form a window perpendicular to the shaft. Hence the light is directed perpendicular to the shaft and provides illumination in that direction instead of head on from the end of the Light Wand.

5. PERFORMANCE STANDARDS

No performance standards have been established for the ITALITE tm Light Wands under section 514 of the Federal Food and Drug Act. However the ITALITE tm Light Wands have been designed to meet the following standards:

Applicable portions of IEC60601-2-18
Manufacturing under an approved Quality System

6. INDICATIONS FOR USE

The ITALITE tm Light Wand is indicated for illumination during joint examinations, arthroscopies, biopsies, in minimally invasive procedures of the knee, shoulder, temporal-mandibular joint, ankle, and elbow .

The ITALITE tm Light Wand is disposable, single use and is intended to be discarded after the procedure. It is supplied clean but not sterile and must be sterilized before use.

The ITALITE tm is for illumination only and is not indicated for

viewing.

It is to be used by physicians only.

7. CONTRA-INDICATIONS

None known at this time.

8. COMPARISON TO PREDICATE DEVICES

The ITALITE tm series of Light Wands have the same device characteristics as the approved predicate devices listed in item 3 above with the commonality of the illumination modality . principles of operation, and materials.

The ITALITE tm series of Light Wands are constructed of materials of the same specifications as the predicate devices to ensure biocompatibility. The ITALITE tm Light Wands conforms to applicable ISO standards. The device will be sold non-sterile , to be sterilized before use by the user. The ability to sterilize the device has been confirmed by the recommended sterilization validation protocol.
Performance tests designed to ensure that the device met all of its functional specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards.

The ITALITE tm Light Wand series device labeling includes instructions for safe and effective use, warnings, cautions and guidance for use. It has therefore shown to be safe and effective.

9. SOFTWARE

The ITALITE tm series of Light Wands have no software or firmware associated with them.

10. LITERATURE REVIEW

A review of the literature pertaining to the safety and effectiveness of the ITALITE tm Arthroscopes has been conducted and appropriate safeguards have been incorporated in the design of the ITALITE tm Light Wands.

11. CONCLUSIONS

The conclusion drawn from these tests is that the ITALITE tm Light Wands are substantially equivalent in safety and efficacy to the predicate devices listed in item 3 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JG Medical Products, LLC
% Multigon Industries, Inc.
William Stern
Official Correspondent
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Yonkers, New York 10701

DEC - 7 2007

Re: K070021
Trade/Device Name: ITALITE™ Model 500-3.1, 550.3.1, 600-3.1, 650-3.1, 450-2.0
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 28, 2007
Received: November 30, 2007

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): k070021

Device Name: ITALITE™ LIGHT WAND

Indications For Use:

The ITALITE tm Light Wand is indicated for illumination during joint examinations, arthroscopies, biopsies, in minimally invasive procedures of the knee, shoulder, temporal-mandibular joint, ankle, and elbow.

The ITALITE tm Light Wand is disposable, single use and is intended to be discarded after the procedure. It is supplied clean but not sterile and must be sterilized before use.

The ITALITE tm is for illumination only and is not indicated for viewing. It is

to be used by physicians only.

Prescription Use ___X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K070021